

REMARKS

This communication is submitted in response to the Office Action dated January 4, 2007.

Claims 1-16 are pending in the subject patent application with claims 1 and 10 being amended herewith and claims 17-26 being cancelled herewith. Claims 2-9 and 11-16 have not been changed relative to their immediate prior version.

Support for the amended claims is found throughout the specification as originally filed, and the amended claims do not introduce any new matter.

The specification has been amended to modify the title for consistency with the claims that remain in the subject application, to delete the objects which were stated in the specification, and to implement grammatical corrections. The objects stated in the specification have been deleted since the claimed invention is not and should not be construed as being limited to only those objects that were stated.

Reconsideration of the subject patent application is respectfully requested in view of the foregoing amendments and the following remarks.

The provisional election that was made without traverse, by telephone, to prosecute the invention of Group I, corresponding to claims 1-16, is hereby affirmed. Claims 17-26, which were withdrawn from further consideration by the Examiner as being drawn to a non-elected invention, have been cancelled without prejudice or disclaimer.

The rejection of claims 1-16 as being unpatentable over Grinberg in view of Krause et al and further in view of Samson is respectfully traversed for the following reasons.

Independent claim 1 recites “an elongate angled outer tubular member comprising ... a bend between said distal end and said proximal end ... and an elongate flexible inner tubular member rotatably disposed in said outer tubular member and comprising ... an elongate tubular body between said distal end of said inner tubular member and said proximal end of said inner tubular member, a cutting configuration at said distal end of said inner tubular member ..., a flexible region along said body disposed in said bend, said flexible region comprising a continuous helical cut formed along a length portion of said body, a coating of adhesive disposed over an outer surface of said body along said length portion, and a heat shrunk sleeve disposed over said length portion with a close diametric fit, with said adhesive bonding said sleeve to said outer surface of said body along said length portion, said flexible region conforming to said bend while transmitting torque to rotate said cutting configuration when said proximal end of said inner tubular member is rotated in forward and reverse rotational directions, said sleeve bonded to said body providing resistance to wind-up and unwinding of said length portion when transmitting torque.” It is submitted that the combination of features recited in independent claim 1 is not obvious from Grinberg in view of Krause et al and further in view of Samson.

Grinberg pertains to a surgical instrument 10 in which the inner tube 14 has a rigid proximal region 17 and a rigid distal region 28 coupled together by a flexible region 16 that accepts the curvature imposed by bend region 13 of outer tube 12. The Examiner refers to column 3, lines 5-16 of Grinberg as disclosing a flexible region “formed by slots in the wall of the shaft”, but in actuality Grinberg discloses the flexible region 16 to be formed of a set of individual, separate and discontinuous, interengaging

ring segments 60 that link the distal region 28 and the proximal region 17 of the inner tube or shaft. Each segment 60 is explicitly disclosed by Grinberg as constituting a ring 64 having tabs 66 and slots 68. The tabs 66 of each segment 60 are received by the slots 68 of the adjacent segment 60. The tabs 66 and slots 68 are configured so that spaces 76 are provided between adjacent segments 60 which allow the tabs 66 to move freely within the slots 68 during rotation of the inner tube 14. In view of Grinberg's explicit teachings, the flexible region 16 cannot properly be construed as being formed by slots in the wall of the shaft as asserted by the Examiner. The individual, separate and discontinuous, ring segments 60 and the free movement of tabs 66 within the slots 68 as disclosed by Grinberg is entirely different from a continuous helical cut formed along a length portion of an elongate tubular body as recited in independent claim 1. Notably, Grinberg teaches away from a continuous helical cut formed along a length portion of a tubular body in that segments 60 are not even made of the same material as the proximal region 17 and the distal region 28 of the inner tube 14. In addition, the geometric configuration of each tab 66 is intentionally non-complementary, non-matching or non-mating with the geometric configuration of the corresponding slot 68 in order to provide a rolling action for the tabs within the slots and a very loose fitting connection between adjacent ring segments 60, thusly providing additional teachings that depart from a continuous helical cut formed along a length portion of a tubular body. The segments 60 being individual, separate and discontinuous, ring segments presents a situation where wind-up and unwinding of a helically cut length portion of a tubular body are not issues. Accordingly, the sheath 74 that Grinberg discloses to surround the segments 60 is only for the purpose disclosed

by Grinberg of covering the openings 76 between adjacent segments 60, and has nothing whatsoever to do with providing resistance to wind-up and unwinding which are not even issues applicable to the inner tube 14 of Grinberg. Grinberg, therefore, cannot properly be construed as disclosing, expressly or inherently, a sleeve providing resistance to wind-up and unwinding of a helically cut length portion of a tubular body when transmitting torque, and Grinberg also does not disclose or suggest a sleeve adhesively bonded to a helically cut length portion of a tubular body for this purpose. Indeed, there are absolutely no teachings or suggestions whatsoever by Grinberg of the sheath 74 being adhesively bonded to the set of ring segments 60 for any purpose, much less for providing resistance to wind-up and unwinding when transmitting torque. It should also be noted that the flexible region recited in claim 1 is required to conform to the bend in the outer member while transmitting torque to rotate the cutting configuration on the inner tubular member when the proximal end of the inner tubular member is rotated in forward and reverse rotational directions, whereas Grinberg does not disclose or suggest that the inner tube 14 is rotatable within the outer tube 12 to transmit torque when rotated in both forward and reverse rotational directions.

The aforementioned deficiencies of Grinberg are not rectified by Krause et al or Samson. In particular, the teachings of Krause et al and Samson are not properly combinable with Grinberg and, even if combined, do not arrive at the claimed invention. Krause et al relates to a flexible shaft 10 for transmitting torque from a rotatably driven end 14 to a driven part 15. There are no teachings or suggestions by Krause et al that the flexible shaft 10 is rotatably disposed in an outer tubular member, much less conforming to a bend in an outer tubular member. Rather, Krause et al discloses

merely that the shaft 10 has a high level of flexibility “to facilitate movement around, over or under an obstacle.” Krause et al illustrates a preferred use of the flexible shaft (Fig. 12), which clearly shows that the shaft is not rotatably disposed in an outer tubular member. Indeed, contrary to the flexible shaft being rotatably disposed in an outer tubular member, it is the intention of Krause et al for the shaft itself to serve as an outer tubular member that receives an inner member, i.e. a guide wire or rod, as further seen in Fig. 12. Although Krause et al discloses a slot 32 cut through the wall 22 of the shaft 10 in a spiral path to impart flexibility, it would not have been obvious to one of ordinary skill in the art at the time of the claimed invention to form the flexible region 16 of Grinberg to have a spiral cut as taught by Krause et al because the spiral cut disclosed by Krause et al as being formed in the shaft 10 is not an equivalent or obvious substitute for the individual, separate and discontinuous ring segments 60 that are the essence of Grinberg’s invention. A primary feature of Grinberg’s flexible region 16 pertains to the intentionally non-complementary, non-matching or non-mating geometric profiles of the tabs 66 and the slots 68 which would be totally eliminated if the ring segments 60 were replaced with the spiral cut 32 as disclosed by Krause et al. The reason proffered by the Examiner as to why it would have been obvious to form the flexible region 16 of Grinberg to have a spiral cut 32 as taught by Krause et al is also without merit. The Examiner states it would have been obvious to employ the continuous helical cut of Krause et al to form the flexible region of Grinberg “in order to enhance the flexibility and torque transmission of the inner member” but, as pointed out above, Grinberg discloses that the geometry of the ring segments 60 provides a very loose fitting connection in which the tabs 66 move freely within the slots 68. The prior

art fails to provide any motivation whatsoever as to why use of a helical cut instead of the segments 60 in Grinberg would provide enhanced flexibility and torque transmission in Grinberg's inner tube 14 over that which Grinberg already discloses. The conclusion reached by the Examiner as to why it would have been obvious to use Krause et al's spiral cut 32 to form the flexible region 16 in Grinberg is purely speculative and can only be based on unfounded assumption and impermissible hindsight.

The Examiner further asserts that Krause et al discloses "a polymeric sleeve over the inner member" (Office Action, page 4, lines 1-2); however, Krause et al does not in fact disclose an actual sleeve over the flexible shaft 10. Krause et al discloses that an elastomer or flexible material can be interposed within the slot 102 cut in the flexible shaft 100 and illustrates this embodiment in Fig. 2. Fig. 2 of Krause et al shows the flexible material only within the slot 102 and not over the outer surface of the flexible shaft 100, thusly demonstrating that Krause et al had in mind an amorphous material as opposed to an actual sleeve structure as is required by the claimed invention.

Accordingly, there are no teachings or suggestions whatsoever by Krause et al of an actual sleeve, let alone a heat shrunk sleeve, disposed over the spiral cut portion of the flexible shaft 100, much less an actual sleeve adhesively bonded to the outer surface of the shaft 100 providing resistance to wind-up and unwinding of the spiral cut portion when transmitting torque. The flexible material interposed within slot 102 is disclosed by Krause et al to further enhance flexibility of the shaft and to alter torsional response or stiffness, but this has nothing whatsoever to do with providing resistance to wind-up and unwinding of the shaft when transmitting torque. Krause et al also teaches that the flexible material can be used for shock absorption or cushioning and that it can

encapsulate the entire shaft to form a tubular construction but, again, this has nothing whatsoever to do with providing resistance to wind-up and unwinding of the shaft. In addition to Krause et al failing to disclose a sleeve as recited in claim 1, Krause et al fails to disclose a coating of adhesive as recited in claim 1.

The Examiner relies on Samson as disclosing an adhesive layer bonding a heat shrunk covering to a helical shaft and asserts it would have been obvious to attach the sheath 74 of Grinberg over the flexible region 16 of Grinberg, as modified by Krause et al to be a spiral cut, with adhesive as disclosed by Samson. Applicant respectfully disagrees with the conclusion reached by the Examiner. First of all, Samson relates to a flexible catheter for being pushed longitudinally into the vascular system and is not concerned with rotation of a flexible inner member within a bent outer member, much less with transmitting torque to rotate a cutting configuration at the distal end of a flexible inner member when the proximal end of the inner member is rotated. The essence of Samson's invention is a helically wound stiffener ribbon 202 disposed within and adhesively attached to an outer tubing member 206 to form a flexible but kink-resistant catheter. The problem addressed by Samson of kinking of a flexible tube catheter when being pushed and advanced longitudinally within the vascular system is totally unrelated to the problems of wind-up and unwinding of a helically cut tubular body when transmitting torque while being rotated within a bent outer tubular member. The fact that Samson's invention resides in the medical field and includes a helically wound ribbon are not sufficient factors to make Samson pertinent to the claimed invention given that Samson's catheter is not intended for rotation within a bent outer tubular member and that its helically wound ribbon is for stiffening and not for torque

transmission. One of ordinary skill in the field of the claimed invention would not look to the teachings of Samson as being applicable to a rotatable inner tubular member having a flexible region that transmits torque when rotated in forward and reverse rotational directions within a bent outer tubular member.

For similar reasons, the outer tubing member 206 of Samson is not analogous to the sleeve recited in claim 1. The outer tubing member 206 has nothing whatsoever to do with providing resistance to wind-up and unwinding of a helically cut length portion of a tubular body since these conditions are irrelevant to Samson's catheter. Samson discloses that the ribbon 202 is adhered to the outer tubing member 206, but only for the express purpose of establishing kink-resistance due to the lack of slippage between the outer tubing member 206 and the ribbon 202. The outer tubing member 206 of Samson being adhesively attached to the helically wound ribbon 202 has nothing whatsoever to do with providing resistance to wind-up and unwinding when transmitting torque since wind-up, unwinding and torque transmission are not issues that even arise in Samson. Samson fails to provide any teachings or suggestions whatsoever which would have made it obvious to one of ordinary skill in the field of applicant's invention to attach the sheath 74 of Grinberg over the flexible region 16 of Grinberg, even if modified to comprise a spiral cut as taught by Krause et al, using an adhesive as taught by Samson. The prior art fails to provide any teachings or suggestions which would lead one to believe that the sheath 74 of Grinberg could be adhesively bonded to a helically cut flexible region and still allow the flexible region to operate to transmit torque when rotated within a bent outer tubular member, let alone when rotated in forward and reverse directions. The limitation in claim 1 of the sleeve bonded to the elongate

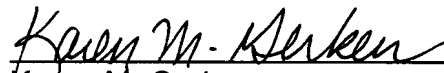
tubular body providing resistance to wind-up and unwinding of the length portion that has the helical cut formed therein can only be arrived at from the prior art by using hindsight interpretation and reconstruction of isolated features of the references based on the teachings of the subject invention itself. Accordingly, independent claim 1 is submitted to be clearly patentable over Grinberg in view of Krause et al and further in view of Samson and should be allowed along with its dependent claims 2-9.

Independent claim 10 recites "an elongate angled outer tubular member comprising ... a bend between said distal end and said proximal end ... and an elongate flexible inner tubular member rotatably disposed in said outer tubular member and comprising ... an elongate tubular body between said distal end and said proximal end of said inner tubular member, a cutting configuration at said distal end of said inner tubular member ..., and a flexible region along said body disposed within said bend, said flexible region comprising an outer wall along an outer diameter surface of said inner tubular member and an inner wall along an inner diameter surface of said inner tubular member, said outer wall being secured to said inner wall, said inner wall comprising a helically cut length portion of said body ..., said outer wall comprising a continuous solid flexible surface covering said helically cut length portion, said flexible region conforming to said bend while transmitting torque to rotate said cutting configuration when said proximal end of said inner tubular member is rotated in forward and reverse rotational directions, said outer wall secured to said inner wall providing resistance to wind-up and unwinding of said helically cut length portion." As pointed out in connection with independent claim 1, Grinberg does not disclose an inner wall comprising a helically cut length portion of a tubular body, does not disclose an outer

wall secured to such an inner wall, does not disclose a flexible region that transmits torque in forward and reverse rotational directions, and does not disclose an outer wall secured to an inner wall providing resistance to wind-up and unwinding of a helically cut length portion of a tubular body. As further discussed above in connection with independent claim 1, it would not have been obvious to replace Grinberg's flexible region 16 constituted of ring segments 60 with the spiral slot 32 disclosed by Krause et al, and it would not have been obvious therefrom to modify Grinberg so that the flexible region 16 is a helically cut length portion of a tubular body. Furthermore, like Grinberg, Krause et al fails to disclose or suggest an outer wall secured to an inner wall, much less an outer wall secured to an inner wall providing resistance to wind-up and unwinding of a helically cut length portion of a tubular body. Samson fails to rectify the aforementioned deficiencies of Grinberg and Krause et al, and it would not have been obvious from Samson to adhesively secure an outer wall to a helically cut length portion of a tubular body to arrive at a structure providing resistance to wind-up and unwinding of the helically cut length portion as recited in claim 10. Accordingly, independent claim 10 is submitted to be clearly patentable over Grinberg in view of Krause et al and further in view of Samson and should be allowed along with its dependent claims 11-16.

In light of the foregoing, all of the claims in the subject patent application are submitted to be in condition for allowance. Action in conformance therewith is courteously solicited. Should any issues in the subject application remain unresolved, the Examiner is encouraged to contact the undersigned attorney.

Respectfully submitted,

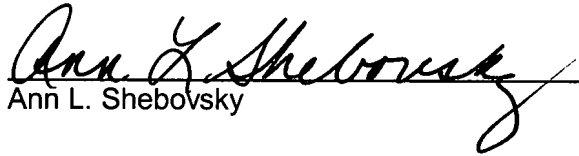


Karen M. Gerken

Registration No. 31,161

EPSTEIN & GERKEN
1901 Research Boulevard, Suite 340
Rockville, Maryland 20850
(301) 610-7634

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop: Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on April 4, 2007.



Ann L. Shebovsky